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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,648	02/11/2002	Daniel Djakiew	P 0280704 DJDA421003	1853
909	7590	10/22/2003	EXAMINER	
PILLSBURY WINTHROP, LLP P.O. BOX 10500 MCLEAN, VA 22102			PRIEBE, SCOTT DAVID	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 10/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/071,648	DJAKIEW, DANIEL	
	Examiner	Art Unit	
	Scott D. Priebe	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-18, drawn to a method for treatment of cancer with a p75 gene, classified in class 514, subclass 44.
- II. Claim 20, drawn to a combination method for treatment of cancer with a p75 gene and an RNA binding protein, classified in class 514, subclasses 2 and 44.
- III. Claim 21, drawn to a combination method for treatment of cancer with a p75 gene and an agent that regulates cell nutrients and or cytokines associated with p75 mRNA stability, classified in class 514, subclass 44 (cannot be classified with respect to agent, no structural information disclosed).
- IV. Claim 23, drawn to a method for treatment of cancer with an RNA binding protein, classified in class 514, subclass 2.
- V. Claim 24, drawn to a method for treatment of cancer with an agent that regulates cell nutrients and or cytokines associated with p75 mRNA stability, cannot be classified, no structural information on agent is disclosed.
- VI. Claims 25-27 and 30, drawn to a method for diagnosing prostate cancer involving measuring p75 mRNA levels, classified in class 435, subclass 6.
- VII. Claim 31, drawn to a method for treatment of cancer with an agent that promotes expression of an endogenous p75 gene, cannot be classified, no structural information on agent is disclosed.

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VIII. Claims 32-34, drawn to a method for treatment of cancer with p75 protein, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions II or III and inventions I, IV or V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because it does not require any particular method of delivering the p75 gene, such as recited in claim 4, nor does it require administration of an tumor apoptosis agent as recited in claim 6. The subcombination has separate utility since either the gene therapy method or method of promoting mRNA stability are disclosed as being usable alone, i.e. usable without the other method.

Inventions I and inventions IV or V are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention I or invention IV or V has separate utility, since invention I is disclosed as usable alone without invention IV or V, and *vice versa*. See MPEP § 806.05(d).

Inventions II or VI and invention III or V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, treatment with RNA binding protein vs. agent that regulates

cell nutrients and/or cytokines have different modes of operation, and they are not disclosed as usable together.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Inventions VI is unrelated to inventions I-V, VII and VIII, they are not disclosed as capable of use together and the diagnostic method has a different mode of operation, different function, and different effect than any of the treatment methods. Inventions VII and VIII are unrelated to each other and unrelated to any of inventions I-V. the agents used in each case are different, and have different modes of operation, and the specification does not disclose that inventions VII or VIII are used with any of inventions I-IV.

Claim 19 links inventions II and III. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 19. Claims 22 and 29 link inventions IV and V. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 22 and 29. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction

requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

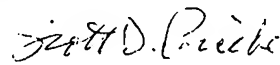
Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for group VI is not required for Groups I-V or VII-VIII, and the search required for each specific treatment group with respect to the agent is not required of the other groups, and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Scott D. Priebe
Primary Examiner
Art Unit 1632